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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,813	01/16/2004	Daniel Robert Blakley	200315907-1	6580

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EXAMINER	
HOLMES, REX R	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,813	BLAKLEY, DANIEL ROBERT	
	Examiner	Art Unit	
	Rex Holmes	3762	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/28/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/28/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/06, 7/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 07/05/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the references that have been struck through have not been considered.

Specification

2. A preliminary examination of this application reveals that it includes terminology which is so different from that which is generally accepted in the art to which this invention pertains. Applicant is required to provide a clarification of these matters or correlation with art-accepted terminology so that a proper comparison with the prior art can be made. Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

3. The term "PT" in the specification (on page 4, lines 29-30, page 5, line 30, page 8, line 21) is used by the specification to mean "the area between the T and P waves" (as shown in figure 2), while the accepted meaning in the art is "TP."

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6, 8, 16-18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 6 recites the limitation "the measuring step" in line 30 on page 11. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 8 recites the limitation "the sampled voltage" in line 6 on page 12. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 16 recites the limitation "the receiver channel" in line 14 on page 13. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 16 recites the limitation "the peak value" in line 16 on page 13. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 16 recites the limitation "the sample" in line 21 on page 13. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 16 is incomplete for omitting an element to digitize the signal, listed in lines 15-17 on page 13.

12. Claim 17 recites the limitation "the signal" in line 24 on page 13. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 18 recites the limitation "the peak voltage" in line 27 on page 13. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 20 recites the limitation "the sampling" in line 4 on page 14. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1-16, 18-23, 25-32 are rejected under 35 U.S.C. 102(b) as anticipated by KYNOR (U.S. Pat. 5,603,321) or, in the alternative, under 35 U.S.C. 103(a) as obvious over KYNOR in further view of STADLER (U.S. Pat. 6,324,421).

18. Regarding Claims 1-9, KYNOR discloses a method for artifact removal using a trigger (Column 3, Lines 1-3) (Column 4, Lines 63-65) (Column 5, Lines 21-23), waiting and sampling an interval of relative inactivity (Column 3, Lines 1-3), and then referencing the sample with the waveform (Column 3, Lines 10-12). KYNOR also discloses that the relative period of inactivity occurs during the "TP" interval (Column 4, Lines 60-63) (Figure 3, 54) and that the "TP" is greater than 0.2 seconds (Figure 3, 54).

19. KYNOR further discloses that the triggering event is the peak R-value in the waveform (Column 4, Lines 63-65), and is followed by negative S peak and the T wave (Column 5, Lines 21-23).

20. It is noted that when the trigger is the R peak and the sample is "TP" electrocardial waveform inherently contains a negative S peak and a T-wave following the R peak, but before the start of "TP".

21. KYNOR discloses that the sampling rate is based on heart rate as determined by the positive R-value (Column 5, Lines 15-35), and that the sample is used to remove artifacts from the waveform (Column 5, Lines 44-62). KYNOR further discloses that the amplitude of the sample (the sample) is used to create an artifact curve with equivalent amplitude (Reference voltage) (Column 5, Lines 44-62) (Figures 4 and 6). KYNOR discloses that the method detects R-waves and isoelectric frequency components in the waveform. (Column 5, Lines 17-20).

22. It is noted that reference electrodes are used to provide a ground that help limit and minimize artifacts in the waveform.

23. Regarding Claims 10-15, KYNOR discloses a system for synthesizing a reference value comprising at least one electrode input representing a electrocardial waveform (Figure 1, 30, Column 2, Lines 60-65), an event detector (Column 3, Lines 1-3) (Column 4, Lines 63-65) (Column 5, Lines 21-23), a timing device (Column 5, Lines 15-36), and a sampling device to determine the reference value (Column 3, Lines 5-12). KYNOR discloses that the reference voltage is substantially zero-volts (Column 4, Lines 49-50), and that the triggering event is the R peak (Column 4, Lines 63-65). KYNOR

further discloses that the event can be an interval of relative inactivity before the QRS complex (Column 5, Lines 37-42). KYNOR also discloses that the sampling device determines the reference value based on the sample and the rate of change in the voltage (amplitude) of the waveform (Column 5, Lines 14-60) (Figures 4 and 6), and an artifact removal system utilizing a computer to analyze and control the system (Column 6, Lines 9-12).

24. Regarding Claims 16 and 18-20, KYNOR discloses a device for recording electrocardial waveforms comprising; an input (Figure 1, 24), a memory element (Figure 1, 42), a processor (Figure 1, 40)), and a voltage generator to generate the value of the sample (Column 5, Lines 44-62), and that device subtracts the value of the sample from the signal (Column 5, Lines 44-62). KYNOR further discloses that the peak value is the R peak (Column 4, Lines 49-50, Claim 4, Column 7, Lines 6-9), and the expected region of inactivity is the TP area of the waveform (Column 4, Lines 60-63) (Figure 3, 54). KYNOR also discloses that the processor adjusts the sampling based on the heart rate as determined by the positive R-values. (Column 5, Lines 15-35).

25. Regarding Claim 21, KYNOR discloses that the device detects R-waves and isoelectric frequency components in the waveform. (Column 5, Lines 17-20).

26. Regarding Claims 22-26, KYNOR discloses a receiver for receiving a waveform comprising a means for receiving an input (Figure 1, 32), a means for detecting an event (Column 3, Lines 1-3) (Column 4, Lines 63-65) (Column 5, Lines 21-23), a means fro measuring a period of time from the event (Column 3, Lines 3-5), and a means for sampling the waveform (Column 3, Lines 10-12).

27. KYNOR further discloses the receiver of claim 22 with a means for detecting the R peak (Column 4, Lines 49-50, Claim 4, Column 7, Lines 6-9), a means for detecting an interval of relative inactivity before an R peak from a previously recorded waveform (Column 5, Lines 37-42) (Column 4, Lines 19-22), and a means to detects R-waves and isoelectric frequency components in waveforms. (Column 5, Lines 17-20).

28. Regarding Claims 27-31, KYNOR discloses a computer-readable media (Column 4, Lines 19-24) for identifying a triggering event (Column 3, Lines 1-3) (Column 4, Lines 63-65) (Column 5, Lines 21-23), sampling during an interval of relative inactivity (Column 3, Lines 5-10) and referencing the sample (Column 3, Lines 10-12).

29. KYNOR discloses that there is a waiting period between the event and the relative period of inactivity that occurs during the "TP" interval (Column 4, Lines 60-63) (Figure 3, 54).

30. KYNOR further discloses that the triggering event is the peak R value (Column 4, Lines 49-50, Claim 4, Column 7, Lines 6-9), followed by negative S peak and the T wave (Column 5, Lines 21-23).

31. Examiner notes that when the trigger is the R peak and the sample is "TP" electrocardial waveform inherently contains a negative S peak and a T-wave following the R peak, but before the start of "TP".

32. Regarding Claim 32, KYNOR discloses supplying a reference voltage substantially equal to the value of the sample (Reference voltage) (Column 5, Lines 44-62) (Figures 4 and 6).

33. KYNOR discloses that the claimed invention can be used to remove artifacts from physiological signals, specifically magnetocardiography signals. The signal that was analyzed in the patent was an electrocardial waveform, even though it was detected by magnetocardiography, since it represents the electrical activity of the heart. Alternatively, KYNOR does not expressly state that the invention disclosed can be used to determine shifts and remove noise from electrocardial waveforms, but it states that it can be used on any physiological signals.

34. STADLER teaches the use of the time-series isoelectric areas (Column 4, Lines 64-67) to locate shifts and remove noise from electrocardial waveforms (Column 18, Lines 64-67, Column 19, Lines 1-7).

35. Regarding Claims 1-23 and 25-32, It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the isoelectric area and system described in KYNOR on an electrocardial waveform as described in STADLER, to determine any shifts and remove any artifacts from electrocardial waveforms.

36. Claim 17 is rejected under 35 U.S.C. 103(a) as obvious over KYNOR.

37. KYNOR discloses the device of claim 16 that subtracts the value of the sample from the signal, in the alternative KYNOR does not explicitly teach that the subtraction is done with an amplifier.

38. KYNOR discloses the claimed invention except for expressly disclosing the use of an amplifier to subtract the waveform from the reference value. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the artifact removal system as taught by KYNOR, with a amplifier since it was known in the art that amplifiers are used to provide a simple and affordable way to compare two signals.

39. KYNOR discloses the claimed invention but does not disclose expressly the use of an amplifier to subtract the waveform from the reference value. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the way the two signals are compared as taught by KRYNOR with the use of an amplifier, because Applicant has not disclosed that amplifier provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with method of comparing the signal as taught by KRYNOR, because it provides a simple way to compare two signals and since it appears to be an arbitrary design consideration which fails to patentably distinguish over KRYNOR.

Therefore, it would have been an obvious matter of design choice to modify KRYNOR to obtain the invention as specified in the claim(s).

40. Claim 24 is rejected under 35 U.S.C. 103(a) as obvious over KYNOR.

41. Regarding Claim 24, KYNOR discloses the receiver of Claim 23, wherein it has a means for detecting negative peaks of the QRS complex (Column 5, Lines 37-43).

42. KYNOR discloses the device of Claim 23, wherein it has a means for detecting negative peaks of the QRS complex, however KYNOR does not explicitly teach that does detect negative peaks.

43. KYNOR discloses the claimed invention but does not disclose expressly the use of a negative peak of the QRS complex as the trigger. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the trigger as taught by KYNOR with the detection of the negative peak, because Applicant has not disclosed that using the negative peak provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the positive peak as taught by KYNOR, because it provides an easy reference to find with simple filters and since it appears to be an arbitrary design consideration which fails to patentably distinguish over KYNOR.

44. Therefore, it would have been an obvious matter of design choice to modify KYNOR to obtain the invention as specified in the claim(s).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

7/20/06

Rex Holmes

George Evanisko

Primary Examiner

7/20/06